

**Remarks**

This paper amends claims 1, 9, 30, and 37. Support for the amendments is found throughout the specification and at least at ¶¶ 12 and 16-17, Examples 1-6 and 8-9, and Figures 1-26. No new matter is added by these amendments. After the amendments set forth herein are entered, claims 1-4, 6-17, and 30-56 are pending and under examination.

**Summary of Interview**

Courtesies extended to Applicants' representative during the telephone interview held on November 20, 2009, are acknowledged with appreciation. The communication mailed November 25, 2009 accurately reflects the subject of the interview. The results of the discussion are incorporated into the arguments below

**Rejection under 35 U.S.C. § 112, First Paragraph**

The rejection of claims 1-4, 6-17 and 30-56 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement is respectfully traversed.

The Examiner acknowledges that the specification is enabling for measuring an amount of unlabeled organic acid and oxygen-18 organic acid using mass spectrometry, but alleges that the specification is not enabling for other methods of measurement. Applicant disagrees with Examiner's assertion. However, in order to expedite prosecution independent claims 1, 9, 30, and 37 have been amended to require that measuring the amount of unlabeled organic acids and oxygen-18 organic acids in the processed sample is accomplished by mass spectrometry; the technique acknowledged by the Examiner to be fully enabled. Consequently, the rejection is traversed and should be withdrawn.

**Rejection of claims under 35 U.S.C. § 102(a)**

Claims 1-3, 7-9 and 12-15 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Leis (J. Chrom. B, 2003, hereinafter “Leis”). Applicant respectfully traverses this rejection.

The Examiner alleges that, because Leis discloses a method of measuring the amount of unlabeled organic acid in a sample by adding oxygen-18 labeled valproic acid (VPA) to a sample suspected of containing unlabeled VPA, claims 1-3, 7-9 and 12-15 are anticipated. As discussed in the Interview and acknowledged by the Examiner, VPA is a mono-carboxylic acid which is not one of the chemical species embraced by the claims. Consequently, Leis does not anticipate the instant claims and this rejection is traversed and should be withdrawn.

**Rejections of claims under 35 U.S.C. § 103(a)**

**Rejection of claims 4, 6, 16 and 17**

Claims 4, 6, 16 and 17 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leis in view of Nguyen et al. (US 2005/0070023, hereinafter “Nguyen”). Applicant respectfully traverses this rejection.

In asserting this rejection, the Examiner relies on Leis as a primary reference. As noted above, Leis fails as a primary reference because Leis fails to disclose a method for measuring the amount of an unlabeled organic acid in a sample for an organic acid class identified in the claims. The Examiner asserts Nguyen as teaching an LC-MS method for detecting oxygen-18-labeled organic acids but, like Leis, Nguyen does not teach such a method for an organic acid as claimed. Accordingly, neither Leis nor Nguyen provide a detection method for the organic acids of the instant claims. This rejection is traversed and should be withdrawn.

Rejection of claims 10, 11 and 46-56

Claims 10, 11 and 46-56 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leis in view of Nguyen as applied to claims 4, 6, 16 and 17 and further in view of Shaw et al. (US 5,686,311, hereinafter “Shaw”). Applicant respectfully traverses this rejection.

As discussed above, neither Leis nor Nguyen provide a method for detecting the organic acids of the instant claims. Shaw fails to remedy this deficiency. The Examiner merely asserts Shaw to demonstrate that abnormal organic acid levels are associated with autism. Accordingly, this rejection is traversed and should be withdrawn.

Rejection of claims 30-45

Claims 30-45 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leis in view of Nguyen and Shaw as applied to claims 10, 11 and 45-56 and further in view of Breakefield et al. (US 5,030,570, hereinafter “Breakefield”). Applicant respectfully traverses this rejection.

As discussed above, the combination of Leis, Nguyen, and Shaw fail to provide a method for detecting the organic acids of the instant claims. Breakefield fails to remedy this deficiency. The Examiner merely asserts Breakefield to demonstrate that the levels of certain organic acids are reduced in the urine of patients with certain metabolic diseases. Accordingly, this rejection is traversed and should be withdrawn.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Prompt and favorable action on the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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